IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO

Erick Jones, as Guardian of the Estate of Amity Stowers, with Aministrator Appointment Pending,
2599 State Route 598
Crestline, OH 44827,

Plaintiff,

v.

BAYER HEALTHCARE PHARMACEUTICALS INC.
c/o Corporation Service Company, Agent
50 West Broad Street, Ste. 1330
Columbus, OH 43215

and

BAYER CORPORATION
c/o Corporation Service Company, Agent
50 West Broad Street, Ste. 1330
Columbus, OH 43215

and

BAYER HEALTHCARE LLC,
c/o Corporation Service Company, Agent
50 West Broad Street, Ste. 1330
Columbus, OH 43215

Defendants.

PLAINTIFF'S COMPLAINT AND DEMAND FOR JURY TRIAL

COMES NOW Plaintiff and undersigned counsel, and alleges as follows:

INTRODUCTION

1. Pursuant to R.C. 2225.02 and R.C. 2305.21, Plaintiff Erick Jones brings this action as he will be appointed Executor of the Estate of Amity Stowers for the exclusive benefit

of the next of kin. A substitution reflecting such will be filed once an Entry Appointing Fiduciary has been issued.

2. This is an action for the wrongful death of Amity Stowers. Amity Stowers was given the gadolinium-based contrast agent Magnevist on September 10, 2009 prior to receiving an MRI scan. She died on March 29, 2017 of pulmonary fibrosis, nephrogenic systemic fibrosis, and end stage renal disease, which were caused by Magnevist.

3. Gadolinium is a highly toxic heavy metal and rare earth element. It does not occur naturally in the human body. The only known route for gadolinium to enter the human body is by injection of a gadolinium-based contrast agent.

4. This is an action for the wrongful death of Amity Stowers, and survivorship claims as a direct and proximate result of Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, advertising, distribution, labeling, and/or sale of the pharmaceutical drug Magnevist, a gadolinium-based contrast agent used in MRIs.

5. Plaintiff maintains that Magnevist was defective, dangerous to human health, unfit and unsuitable to be marketed and sold in commerce, and lacked proper warnings and directions as to the dangers associated with its use.

6. The gadolinium from Magnevist does not leave the patient's body as readily as promised, and instead can be retained indefinitely or permanently in multiple organs and soft tissues (e.g., lungs, brain, heart, liver, kidney, bones, and skin) in patients with an estimated glomerular filtration rate ("eGFR") above 30. This gadolinium, a toxic heavy metal, caused fibrosis in organs, bone, and skin, other adverse reactions, and crossed the blood-brain barrier and deposited in the neuronal nuclei of Amity Stowers's brain.

JURISDICTION AND VENUE

7. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the amount in controversy exceeds $75,000, exclusive of interest and costs, and because Defendants are all incorporated and have their principle places of business outside of the state in

which the Plaintiff resides. The subject drug administration occurred in Ohio, Amity Stowers was primarily treated in Ohio, and she passed away in Ohio.

8. There is a complete diversity of citizenship between Plaintiff and Defendants. Plaintiff is a resident and citizen of and is domiciled in the State of Ohio. As set forth fully below, all Defendants are entities organized in states other than the State of Ohio, have their principle place of business in states other than Ohio, and none of the Defendants is a citizen or resident of the State of Ohio.

9. The Court also has supplemental jurisdiction pursuant to 28 U.S.C. § 1367.

10. This Court has personal jurisdiction over all Defendants, each of which is licensed to conduct and is systematically and continuously conducting business in this state, and specifically targeted Ohio including, but not limited to, the marketing, researching, testing, advertising, selling, and distributing of Magnevist, to the residents of this state, including Amity Stowers.

11. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because the Defendants conduct business in the State of Ohio and are subject to personal jurisdiction in this State. Defendants sell, advertise, market, and or distribute Magnevist within the State of Ohio, and do substantial business in this state and within this District.

12. Defendants developed, manufactured, promoted, marketed, tested, researched, distributed, warranted, and sold the subject drug Magnevist in Ohio.

PARTIES

13. Amity Stowers was a natural person and at all relevant times a resident and citizen of the State of Ohio.

14. Amity Stowers was injected with the linear gadolinium-based contrast agent Magnevist prior to receiving MRIs on or around September 2009.

15. Unbeknownst to Amity Stowers and contrary to the Defendant's promotion of GBCAs as benign contrast agents that harmlessly exit the body shortly after administration in patients who have an eGFR above 30, Ms. Stowers retained gadolinium in her body years after

being administered the GBCAs, resulting in permanent physical and emotional injuries, and ultimately death.

16. Amity Stowers suffered gadolinium retention in multiple organs and soft tissues (e.g., lungs, brain, heart, liver, kidney, bones, and skin). The gadolinium, a toxic heavy metal, caused fibrosis in Amity Stowers's organs, bone, and skin, other adverse reactions, and crossed the blood-brain barrier and deposited in the neuronal nuclei of her brain.

17. At the time of Amity Stowers's use of the linear GBCAs at issue, she had an eGFR above 30, and the GBCA manufacturers chose to only provide warnings to patients with reduced renal function (eGFR below 30). Defendants failed to appropriately and adequately inform or warn Amity Stowers and her healthcare providers about the risks of gadolinium retention in patients with her eGFR.

18. Defendants BAYER HEALTHCARE PHARMACEUTICALS INC., BAYER CORPORATION, and BAYER HEALTHCARE LLC (collectively "Manufacturing Defendants") manufacture, test, market, advertise, and sell the linear GBCA named Magnevist.

19. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. is a Delaware company with its principle place of business in New Jersey. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. is a resident and citizen of both Delaware and New Jersey. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. is duly authorized to conduct business in the State of Ohio and does significant business in the State of Ohio. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. is engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing Magnevist into interstate commerce, either directly or indirectly through third parties or related entities. This Court has personal jurisdiction over BAYER HEALTHCARE PHARMACEUTICALS INC. under the doctrine of specific jurisdiction because the subject incident arises out of and relates to BAYER HEALTHCARE PHARMACEUTICALS INC.'s forum-related activities – namely the marketing, advertising, and sale of Magnevist to Amity Stowers and her doctors.

20. Defendant BAYER CORPORATON is an Indiana corporation with its headquarters located in Pennsylvania. Defendant BAYER CORPORATION is duly authorized to conduct business in the State of Ohio and does significant business in the State of Ohio. Defendant BAYER CORPORATION is engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing Magnevist into interstate commerce, either directly or indirectly through third parties or related entities. This Court has personal jurisdiction over BAYER CORPORATION. under the doctrine of specific jurisdiction because the subject incident arises out of and relates to BAYER CORPORATION's forum-related activities – namely the marketing, advertising, and sale of Magnevist to Amity Stowers and her doctors. BAYER CORPORATION has facilities in Toledo, Ohio and Cleveland, Ohio.

21. Defendant BAYER HEALTHCARE LLC is a Delaware LLC with its headquarters in New Jersey. Defendant BAYER HEALTHCARE LLC is duly authorized to conduct business in the State of Ohio and does significant business in the State of Ohio. Defendant BAYER HEALTHCARE LLC is engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing Magnevist into interstate commerce, either directly or indirectly through third parties or related entities. This Court has personal jurisdiction over BAYER HEALTHCARE LLC under the doctrine of specific jurisdiction because the subject incident arises out of and relates to BAYER HEALTHCARE LLC's forum-related activities – namely the marketing, advertising, and sale of Magnevist to Amity Stowers and her doctors. BAYER HEALTHCARE LLC has offices in the state of Ohio and is registered to do business in Ohio, but no member or owner of BAYER HEALTHCARE LLC is domiciled in Ohio. The officers of BAYER HEALTHCARE LLC reside in Pennsylvania, New Jersey, Kansas, and California. BAYER HEALTHCARE LLC's members and owners are Delaware corporations or limited liability companies. For any member of BAYER HEALTHCARE LLC that is also a limited liability company, all of their underlying members and owners are Delaware or European corporations or limited partnerships.

22. Defendants are authorized to do business in the state of Ohio and derive substantial income from doing business in this state.

23. Upon information and belief, Defendants specifically targeted the State of Ohio for its sales of Magnevist, thus invoking the benefits and protections of its laws.

24. Upon information and belief, Defendants did act together to design, sell, advertise, manufacture, promote, and/or distribute Magnevist, with full knowledge of its dangerous and defective nature.

FACTS COMMON TO ALL CAUSES OF ACTION

25. The type of gadolinium retention and Nephrogenic Systemic Fibrosis sustained by Amity Stowers occurs in patients eGFRs greater than 30, who develop persistent symptoms that arise hours to months after the administration of a linear GBCA. At the time of her MRI scan, Amity Stowers's eGFR was approximately 35. Plaintiff had no preexisting disease or subsequently developed non-GBCA related disease to account for the symptoms she sustained. Gadolinium retention can be a progressive condition for which there is no known cure. The gadolinium that Amity Stowers was injected with was retained in her body and resulted in fibrosis in her organs, skin, and bones, retained gadolinium in the neuronal nuclei of her brain, and related injuries.

26. During the years that Defendants manufactured, marketed, distributed, sold, and administered linear gadolinium-based contrast agents, there have been numerous case reports, studies, assessments, papers, peer reviewed literature, and other clinical data that have described and/or demonstrated gadolinium retention in connection with the use of linear gadolinium-based contrast agents.

27. Defendants failed to warn Amity Stowers and her healthcare providers about the serious health risks associated with linear gadolinium-based contrast agents and failed to disclose the fact that there were safer alternatives (e.g., macrocyclic agents instead of linear agents).

28. As a direct and proximate result of receiving injections of linear gadolinium-based contrast agents manufactured, distributed, marketed, and/or sold by Defendants, Amity

Stowers developed gadolinium retention resulting in fibrosis in her organs, skin, and bones, retained gadolinium in her brain, related injuries, and death.

29. Defendants have repeatedly and consistently failed to advise consumers and their healthcare providers of the causal relationship between linear gadolinium-based contrast agents and gadolinium retention resulting in fibrosis in the organs, skin, and bones, retained gadolinium in the brain, and related injuries. Defendants knew or should have known of the risks posed by linear gadolinium-based contrast agents to individuals with eGFRs greater than 30.

30. Had Amity Stowers and/or her healthcare providers been warned about the risks associated with linear gadolinium-based contrast agents, she would not have been administered linear gadolinium-based contrast agents and would not have been afflicted with gadolinium retention resulting in fibrosis in her organs, skin, and bones, retained gadolinium in her brain, related injuries, and death.

31. Had Plaintiff not taken Magnevist, Plaintiff would not have suffered injuries and damages as set forth herein. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered physical and emotional damages, mental anguish, and death.

32. Had Plaintiff and her medical providers been adequately warned of the risks associated with their GBCAs, Plaintiff would not have used the GBCAs or agreed to being administered with these drugs.

33. As a direct and proximate result of Amity Stowers being administered linear gadolinium-based contrast agents, she suffered severe physical injury and pain and suffering, including, but not limited to, gadolinium retention resulting in fibrosis in her organs, skin, and bones, retained gadolinium in her brain, and related injuries, and ultimately death.

34. As a direct and proximate result of being administered linear gadolinium-based contrast agents, Amity Stowers suffered significant pain, mental anguish, and emotional distress.

35. As a direct and proximate result of being administered linear gadolinium-based contrast agents, Amity Stowers also incurred medical and funeral expenses and other economic damages.

36. Had Plaintiff and/or her healthcare providers been warned about the risks associated with linear gadolinium-based contrast agents, he would not have been administered linear gadolinium-based contrast agents and would not have been afflicted with gadolinium retention resulting in fibrosis in his organs, skin, and bones, retained gadolinium in his brains, and related injuries.

37. The manufacturers of the linear GBCAs have known since the FDA approval of Magnevist that their drugs could cause retention of toxic gadolinium. Their claims to the public and healthcare providers have been misleading and false.

38. In 1984 – prior to FDA approval – the inventors of linear gadolinium-based contrast agents claimed that their product, Gd-DTPA, did not cross the blood-brain barrier, and that the bonds between the toxic gadolinium and its protective coating did not break inside the body. Additionally, they claimed that there would be no toxic gadolinium residue left behind to cause illness.[1]

39. There are two basic types of contrast agents differentiated by their chemical structure – linear agents and macrocyclic agents. The main difference is that the linear agents do not fully surround the gadolinium ion, whereas the macrocyclic agents form a more complete ring around the gadolinium ion which creates a stronger bond. The linear agents include: Magnevist (manufactured by Bayer), Omniscan (manufactured by GE), OptiMark (manufactured by Guerbet/Mallinckrodt/ Liebel-Flarsheim), and MultiHance (manufactured by Bracco).

40. Magnevist, a linear agent, was the first gadolinium-based contrast agent to reach the market after receiving FDA approval in 1988.

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[1] Brasch RC. Inherent contrast in magnetic resonance imaging and the potential for contrast enhancement – the 1984 Henry Garland lecture. *West J Med.* 1985 Jun; 142:847-853.

41. In 1988 it was recognized in a paper that gadolinium was breaking free from the bonds in the linear-based contrast agents and this was in part due to the competition for its protective layer (chelate) by other essential metals in the body such as zinc, copper, and iron.[2] Furthermore, emerging science showed that the bond between toxic gadolinium and its chelate or cage (Gd-DTPA) became very weak and separates easily in low pH conditions such as those found in many compartments of the human body including extracellular fluid spaces.

42. Stability differences among gadolinium contrast agents have long been recognized in laboratory (in vitro), and deposition of toxic gadolinium in tissues has been described in animal models. The first major study that showed deposition in humans appeared in 1998 regarding patients with renal failure and later in 2004 in patients with normal renal function.[3]

43. Laboratory (in vitro) studies assessing the stability of each gadolinium-based contrast agent in human blood were performed and demonstrated that, over time, greater percentages of gadolinium were released from linear agents as compared to the macrocyclic agents.[4]

44. The lack of stability seen within the linear agents was dismissed as an issue by the defendants claiming that the GBCA's were excreted out of the body according to the drug's claimed half-life, before the chelate could release the toxic gadolinium. However, it was later noted that some conditions could cause prolonged retention of the contrast agents, thus allowing more toxic gadolinium to be released in the bodies of patients. In addition, a delayed elimination phase of the gadolinium-based contrast agents would later be discovered.

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[2] Huckle JE, Altun E, Jay M, et al. Gadolinium deposition in humans: when did we learn that gadolinium was deposited in vivo? *Invest. Radiol.* 2016; 51:236-240.

[3] *Id.*

[4] Tweedle MF, Eaton SM, Eckelman WC, et al. Comparative chemical structure and pharmacokinetics of MRI contrast agents. *Invest. Radiol.* 1988; 23 (suppl 1): S236-S239; *see also* Frenzel T, Lengsfeld P, Schimer H, et al. Stability of gadolinium-based magnetic resonance imaging contrast agents in serum at 37 degrees C. *Invest. Radiol.* 2008; 43:817-828.

45. Peer-reviewed articles on the deposition of gadolinium in animals with normal renal function, some illustrating deleterious consequences, have been published as early as 1984.[5]

46. After the FDA approval of Bayer's Magnevist (a linear contrast agent) in 1993 the preclinical safety assessment and pharmacokinetic data were published describing its pharmacokinetics in rats, rabbits, and cynomolgus monkeys. These studies noted that while toxic gadolinium was no longer detectable in the blood 7-days after administration, quantifiable concentrations of gadolinium were persistent in both the renal cortex and areas around bone cartilage.[6]

47. The first report of toxic gadolinium retention in humans may have been presented in September 1989, a little over 1 year after the approval of Magnevist. Authors *Tien et al.* reported that intracerebral masses "remained enhanced on MRI images obtained 8 days after injection of gadolinium DTPA dimeglumine (Magnevist)."[7] Subsequent chemical analysis revealed that a high concentration of gadolinium remained in the tissue.

48. Defendants knew that their linear GBCAs did not have very stable bonds and could come apart easily causing significant toxicity in humans. Defendants have known about the risks that linear gadolinium-based contrast agents pose to people with normal or near normal kidney function for years. Pharmacokinetic studies in 1991 indicated that gadolinium retention was occurring in people with normal renal function.[8]

49. In 2004, gadolinium was shown to be deposited in the resected femoral heads (bones) of people who had undergone gadolinium MRI studies.[9] Since then, studies have

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[5] Weinman HJ, Brasch RC, Press WR, et al. Characteristics of gadolinium-DTPA complex: a potential NMR contrast agent. *AJR Am J Roentgenol.* 1984; 142: 619-624.
[6] Harpur ES, Worah D, Hals PA, et al. Preclinical safety assessment and pharmaco-kinetics of gadodiamide injection, a new magnetic resonance imaging contrast agent. *Invest Radiol.* 1993; 28 (suppl 1): S28-S43.
[7] Tien RD, Brasch RC, Jackson DE, et al. Cerebral Erdheim-Chester disease: persistent enhancement with Gd-DTPA on MR images. *Radiology.* 1989; 172:791-792.
[8] Schumann-Giampieri G, Krestin G. Pharmacokinetics of Gd-DTPA in patients with chronic renal failure. *Invest Radiol.,* 1991; 26:975-979.
[9] Gibby WA, Gibby KA, Gibby WA. Comparison of Gd DTPA-BMA (Magnevist) versus Gd HP-DO3 (ProHance) retention in human bone tissue by inductively coupled plasma atomic emission spectroscopy. *Invest Radiol.,* 2004; 39:138-142.

continued to indicate that gadolinium remains within people's bodies long after the suggested half-life.

50. Despite this well-documented evidence of gadolinium retention, Defendants have continuously failed to warn consumers and their healthcare providers on the label of their products, or anywhere that a patient or physician could be informed.

51. Dermatologists, nephrologists, and other scientists connected the administration of linear gadolinium-based contrast agents to a rapidly progressive, debilitating and often fatal condition called gadolinium-induced "Nephrogenic" Systemic Fibrosis (NSF), prompting the Food and Drug Administration (FDA) to issue a black box warning regarding the release of toxic gadolinium from the linear contrast agents in people with eGFRs under 30, and its long-term retention in the bodies of animals and humans (for patients with abnormal kidney function) on all gadolinium-based contrast agents in 2007.

52. Defendants corrected their label to include contraindications for use in people with kidney disease and acute kidney injury and eGFR lower than 30.

53. There were over 500 NSF cases reported and estimated to be well over a thousand non-reported. There was a prior MDL and other litigation involving NSF against the defendants in the current litigation. A trial in that litigation resulted in a verdict in favor of the plaintiff and against GE. The litigation resolved and the MDL was formally closed in 2015. Due to the new black box warning in the GBCA's labelling, doctors stopped using GBCAs in patients with eGFRs below 30. However, the warnings for patients with eGFRs above 30 remained unchanged until May 15, 2018, and as a result the linear GBCAs continued to be widely used and marketed notwithstanding the Defendants' knowledge of the dangers of the product. This case and the others pending throughout the country involve widespread fibrosis and other symptoms in the bodies of patients with eGFRs above 30.

54. The vast majority of the medical community was not aware, until recently, of any disease that was associated with gadolinium other than NSF, which was defined as only occurring in patients with eGFRs below 30.

55. Gadolinium toxicity is, therefore, an underreported and underdiagnosed condition. Over the past several years (since the link between gadolinium-based contrast agents and NSF was acknowledged) patients with normal renal function have been forming advocacy groups and coming forward to create awareness for their condition. Symptomatic patients often have documentation of high levels of gadolinium in their blood and urine long after their exposure to gadolinium-based contrast agents. Many patients also have tissue biopsies of various parts of their body that show additional evidence of retained gadolinium years after their exposure.

56. Some patients sent letters with research data to the FDA, warning about the occurrence of gadolinium toxicity in those with normal renal function following injections of gadolinium-based contrast agents.

57. In 2013, while examining non-contrast enhanced MRI images, Japanese researchers found evidence of retained gadolinium in the brains of patients with normal renal function that had previously received one or more injections of gadolinium-based contrast agents up to several years prior. They found that the brain had hyperintense signals in critical areas of the brain.[10]

58. These findings were confirmed by scientists at the Mayo Clinic in 2014 when autopsy studies were performed on 13 deceased individuals, all of whom had normal or near normal renal function and who had received six or more injections of gadolinium-based contrast agents in the years prior. Up to 56 mcg of gadolinium per gram of desecrated tissue were found within the brains of these patients.[11]

59. In July of 2015, in response to the Mayo Clinic study's findings, the FDA issued a new public safety alert stating that the FDA is evaluating the risk of brain deposits from repeated use of gadolinium-based contrast agents used in MRIs.

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[10] Kanda T, Ishii K, Kawaguchi H, et al. High signal intensity in the dentate nucleus and globus pallidus on unenhanced T1-weighted MR images: relationship with increasing cumulative dose of a gadolinium-based contrast material. *Radiology*. 2014; 270: 834-841.

[11] McDonald RJ, McDonald JS, Kallmes DF, et al. Intracranial gadolinium deposition after contrast-enhanced MR imaging. *Radiology*. 2015; 275:772-782.

60. In September 2017, the FDA's medical advisory committee voted 13 to 1 in favor of adding a warning on labels that gadolinium can be retained in some organs, including the brain, even in patients with healthy kidneys.

61. As elaborated above, Defendants discovered newly acquired information after the FDA's initial approval of Magnevist's labels regarding the risks and dangers of retention and physical injuries associated therefrom of linear gadolinium-based contrast agents. This information, regarding gadolinium's potential for retention, was unknown to the FDA when it approved the label. Defendants failed to warn Amity Stowers and her healthcare providers about the serious health risks associated with linear gadolinium-based contrast agents and failed to disclose the fact that there were safer alternatives (e.g., macrocyclic agents instead of linear agents). Therefore, it was reasonably foreseeable that that Magnevist would cause gadolinium retention, fibrosis, related injuries, and death.

62. Defendants could have and should have used a Changes Being Effected supplement to amend their label/instructions with this newly acquired information.

63. In December 2017 the FDA required a new class warning and other safety measures for all GBCAs for MRIs concerning gadolinium remaining in patients' bodies, including the brain, for months to years after receiving these drugs. The FDA required Defendants to develop and implement a patient Medication Guide, and requiring Defendants to conduct human and animal studies to further assess the safety of these contrast agents.

64. In May 2018, the GBCA manufacturers (at the direction of the FDA) finally issued a joint warning to patients with normal kidney function. This new "Important Drug Warning" issued by Bayer, GE, Bracco, and Guerbet included the following:

a. "Subject: Gadolinium from GBCAs may remain in the body for months to years after injection;"

b. A new class warning, patient counseling, and a medication guide;

c. Warning that gadolinium is retained for months to years in several organs;

d. Warning that the highest concentrations of retained gadolinium are found in

bone, followed by organs (brain, skin, kidney, liver, and spleen);

e. Warning that the duration of gadolinium retention is longest in bone and varies by organ;

f. Warning that linear GBCAs cause more retention than macrocyclic GBCAs;

g. Warning about reports of pathological skin changes in patients with normal renal function;

h. Warning that adverse events involving multiple organ systems have been reported in patients with normal kidney function;

i. Warning that certain patients are at higher risk:

   i. patients with multiple lifetime doses;

   ii. pregnant patients;

   iii. pediatric patients;

   iv. patients with inflammatory process;

j. Instructions for health care providers to advise patients that:

   i. Gadolinium is retained for months or years in brain, bone, skin, and other organs in patients with normal renal function;

   ii. Retention is greater following administration of linear GBCAs than following administration of macrocyclic GBCAs.

The Warning deliberately downplays the state of the evidence concerning the health effects of gadolinium retention.

65. This "Dear Health Care Provider" letter is the first time that Defendants made any effort to warn the medical community or the general public about the significant risks identified with the use of linear GBCAs.

66. Defendants are estopped from asserting a statute of limitations defense because of their fraudulent concealment of the true character, quality, and nature of their linear GBCAs. Defendants were under a duty to disclose the true character, quality, and nature of their linear GBCAs because this was non-public information over which Defendants had and continue to

have exclusive control, and because Defendants knew that this information was no available to the Plaintiff, medical providers, and/or to their facilities. Defendants are estopped from relying on any statute of limitations because of their intentional concealment of those facts.

67. Amity Stowers's illnesses and death were a direct and proximate result of the negligence of each Defendant and/or its predecessor-in-interest in that said entities manufactured, produced, sold and/or otherwise placed into the stream of commerce, Magnevist, which Defendants knew, or in the exercise of ordinary care should have known, was deleterious and highly harmful to Amity Stowers's health and well-being. Defendants were negligent in one, some or all of the following respects, among others, same being the proximate cause of Amity Stowers's illnesses and/or death:

a. in failing to timely and adequately warn Amity Stowers of the dangerous characteristics and serious health hazards associated with exposure to Magnevist;
b. in failing to place timely and adequate warnings on the containers of said Magnevist;
c. in marketing Magnevist as safe for use in people with normal kidney function;
d. in failing to recall and/or remove said Magnevist despite knowledge of the unsafe and dangerous nature of it; and
e. in failing to warn of gadolinium retention in people with normal or near-normal kidney function, and/or with eGFR above 30.
f. Failing to adequately and correctly warn the Plaintiff, the public, and the medical and healthcare communities of the dangers of their GBCAs with respect to the risk of gadolinium retention;
g. Failing to disclose their knowledge that gadolinium is retained for months to years in several organs;
h. Failing to disclose their knowledge that higher concentrations of retained gadolinium are found in bone, followed by organs (lungs, brain, skin, kidney, liver, and spleen);

i. Failing to disclose their knowledge that gadolinium retention is longest in bone and varies by organ;

j. Failing to disclose their knowledge that linear GBCAs cause more retention than macrocyclic GBCAs;

k. Failing to disclose their knowledge about adverse event reports involving multiple organ systems in patients with eGFRs above 30;

l. Failing to disclose their knowledge that certain patients are at higher risk of adverse effects from linear GBCAs;

m. Failing to disclose their knowledge of adverse health effects patients who've retained gadolinium develop;

n. Failing to disclose their knowledge that gadolinium has a tendency to cross the blood-brain barrier and deposit in the neuronal nuclei of the brain;

o. Manufacturing, producing, promoting, formulating, creating, and/or designing Magnevist without thoroughly, adequately, and/or sufficiently testing it – including pre-clinical and clinical testing and post-marketing surveillance – for safety and fitness for use and/or sangers and risks;

p. Marketing Magnevist to Plaintiff, Plaintiff's healthcare providers, the public, and the medical and healthcare professions without adequately and correctly warning and/or disclosing the existence, severity, and duration of known or knowable side effects from the retention of gadolinium in the brain, skin, organs, and bones;

q. Marketing Magnevist to Plaintiff, her healthcare providers, the public, and the medical and healthcare professions without providing adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, Magnevist;

r. Marketing Magnevist to Plaintiff, herhealthcare providers, the public, and the medical and healthcare professions without proper warnings and adequate

warnings or labeling regarding adverse side effects and health risks associated with the use of Magnevist and the comparative severity and duration of such adverse effects;

s. Advertising and recommending Magnevist without sufficient knowledge of its safety profile;

t. Advertising and recommending Magnevist without proper or adequate rate of incidence of the prevalence of gadolinium retention and associated side effects;

u. Representing to Plaintiff, Plaintiff's healthcare providers, the public, and the medical and healthcare professions that Magnevist was superior to other commercially available products designed to provide the same MRI scan image contrast, when in fact it was not;

v. Designing, manufacturing, producing, and/or assembling Magnevist in a manner that was dangerous to its users;

w. Concealing information from Plaintiff, Plaintiff's healthcare providers, the public, other medical and healthcare professionals, and the FDA that Mgnevist was unsafe, dangerous, and/or nonconforming with FDA regulations;

x. Concealing from and/or misrepresenting information to Plaintiff, Plaintiff's healthcare providers, other medical and healthcare professionals, or/or the FDA concerning the existence and severity of the risks and dangers of Magnevist, as compared to other commercially available MRI contrast agents;

y. Encouraging the sale of Magnevist either directly or indirectly, orally or in writing, to Plaintiff and Plaintiff's healthcare providers without warning about the need for more comprehensive and regular medical monitoring than usual to ensure early discovery of potentially serious side effects; and

z. Representing to physicians, including but not limited to Plaintiff's prescribing physicians, that Magnevist was safe and effective as well as without potentially serious side effects.

68. As a direct and proximate result of Defendants' failure to warn or to warn adequately, nonconformance to representation, defects in design, manufacture, and/or construction, Amity Stowers suffered injury, illness, disabilities, and death.

FIRST CAUSE OF ACTION

(Against All Defendants)

WRONGFUL DEATH (Ohio Rev. Code 2125.01)

69. Plaintiff incorporates by reference and realleges each paragraph set forth above.

70. As a direct and proximate result of Defendants actions and inactions as set forth above, Amity Stowers suffered a wrongful death on March 29, 2017 at the age of 42.

71. As a further direct and proximate result of Defendants acts and omissions and the wrongful death of Amity Stowers, her next of kin have suffered mental anguish and pecuniary and non-pecuniary losses, including loss of support, consortium, love, services, care, assistance, attention, protection, advice, guidance, counsel, instruction, training, and education.

72. As a further direct and proximate result of the acts and omissions of Defendants and the wrongful death of Amity Stowers, the Estate has incurred reasonable burial and funeral expenses.

SECOND CAUSE OF ACTION

(Against All Defendants)

PRODUCT LIABILITY STATUTES (Survivorship)

73. All of the allegations contained in the previous paragraphs are realleged herein.

74. In addition to the above-delineated counts and causes of action, Plaintiff alleges in based on the above acts and/or omissions, statutory product liability claims pursuant to the provisions contained in the Ohio Revised Code §§ 2307.71 to 2307.80, including § 2307.78, as it applies to distributors and suppliers. In particular, these statutory product liability claims include failure to warn or to warn adequately, nonconformance to representation, and defects in design, manufacture, and/or construction. Specifically, Plaintiff alleges the following:

a. The manufacturers, distributors, and/or suppliers knew, or in the exercise of

reasonable care, should have known about the risks associated with the linear GBCA Magnevist and that caused harm for which Plaintiff seeks to recover damages. The manufacturers, distributors, and/or suppliers failed to provide the warning or instruction and/or adequate warning or instruction that a manufacturer, distributor, and/or supplier exercising reasonable care would have provided concerning that risk, in light of the likelihood that gadolinium from Magnevist would cause harm of the type for which Plaintiff seeks to recover damages. The defects existed at the time the Magnevist left the control of the manufacturers, distributors, and/or suppliers;

b. At a relevant time after the Magnevist manufactured, distributed, and/or supplied by Defendants left the control of the manufacturers, distributors, and/or suppliers, the manufacturers, distributors, and/or suppliers knew or, in the exercise of reasonable care, should have known about the risks that are associated with the Magnevist and that caused harm for which Plaintiff seeks to recover damages. The manufacturers, distributors, and/or suppliers failed to provide the post marketing warning or instruction that a manufacturer, distributor, and/or supplier exercising reasonable care would have provided concerning that risk, in light of the likelihood that gadolinium from Magnevist would cause harm of the type for which Plaintiff seeks to recover damages and in light of the seriousness of that harm;

c. Defendants manufactured, distributed, and/or supplied Magnevist that did not conform, when it left the control of the manufacturers, distributors, and/or suppliers, to representations made by the manufacturers, distributors, and/or suppliers; and

d. Defendants manufactured, distributed, and/or supplied Magnevist, a GBCA that was more dangerous than an ordinary consumer would expect when used in an intended or reasonably foreseeable manner, and the foreseeable risks associated

with Magnevist exceeded the benefits associated with that design or formulation. These defects existed at the time the Magnevist left the control of the manufacturers, distributors, and/or suppliers.

75. As a purchaser and user, Plaintiff and/or her healthcare providers reasonably relied on the misrepresentations and omissions.

76. As a direct and proximate result of Defendants' failure to warn or to warn adequately, nonconformance to representation, defects in design, manufacture, and/or construction, Plaintiff suffered injury, illness, and disabilities.

PUNITIVE DAMAGES

77. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

78. At all times relevant herein, Defendants:

a. knew that their GBCA was dangerous;

b. concealed the dangers and health risks from Amity Stowers, her physicians, pharmacists, other medical providers, the FDA and the public at large;

c. made misrepresentations to Amity Stowers, her physicians, pharmacists, hospitals and medical providers and the public in general as previously stated herein as to the safety of their GBCA; and

d. with full knowledge of the health risks associated with their GBCA and without adequate warnings of the same, manufactured, designed, formulated, testing, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold their GBCA for routine use.

79. Defendants, by and through officers, directors, managing agents, authorized sales representatives, employees and/or other agents who engaged in malicious, fraudulent and oppressive conduct toward Plaintiff and the public, acted with willful and wanton and/or conscious and/or reckless disregard for the safety of Plaintiff and the general public.

80. Defendants consciously and deliberately engaged in wanton disregard of the

rights and safety of the Plaintiff.

81. Defendants had actual knowledge of their GBCA's defective nature and capacity to cause injury including, but not limited to, retention of gadolinium in organs and tissues (e.g., brain, heart, liver, kidney, bones, and skin), resulting fibrosis in organs, bone, and skin, and gadolinium's tendency to cross the blood-brain barrier and deposit in the neuronal nuclei of the brain.

82. Amity Stowers's injuries and death were a result of fraud, malice, and/or gross negligence on the part of the Defendants.

83. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff is entitled to a recovery of punitive damages.

WHEREFORE, Plaintiff demands judgement against Defendants, and each of them, jointly and severally, for compensatory damages in an amount in excess of Twenty-five Thousand Dollars ($25,000), for the costs expended herein, for prejudgment interest from the date of Amity Stowers's exposure to Magnevist, and post-judgment interest on the judgment at the rate allowed by law, and for such other and further relief, both at law and inequity, general and special, this Court deems just and equitable, including punitive damages for the intentional, egregious, and reckless misconduct of Defendants.

Dated: March 29, 2019

/s/ Anne M. Valentine
Anne M. Valentine (0028286)
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JURY DEMAND

Plaintiff demands that all issues of fact in this case be tried to a properly impaneled jury.

/s/ Anne M. Valentine
Anne M. Valentine